

REMARKS

Claims 1-20 were pending. Claims have been amended, claims 1 and 14-20 have been cancelled. Claims 21-27 are newly presented. No new matter has been introduced.

Claim Objections

Claims 1, 2 and 6 are objected to for informalities.

Applicant thanks the examiner for the suggested amendments. The claims have been amended.

Rejections under 35 USC §101

Claims 17-20 are rejected under §101 because the claimed invention is directed to non-statutory subject matter.

Claims 17-20 have been canceled.

Rejections under 37 USC §102

Claims 1-5 and 11-13 are rejected under §102(e) as anticipated by Boecker et al (2004/0098009).

Claims 6-10 are rejected under §102(e) as anticipated by Boecker et al (2004/0092995).

Claims 14 and 16 are rejected under §102(e) as anticipated by Dubowsky et al (2003/0210811).

Rejections under 35 USC §103

Claims 15 stands rejected under §103(a) as obvious over Dubowky (2003/0210811) and further in view of Boecker et al (2004/0098009).

The prior art

Both Boecker '009 and Boecker '995 disclose that "if the cartridge 800 uses an analyte detecting member arrangement where the analyte detecting members are on a substrate attached to the bottom of the cartridge, there may be through holes (as shown in FIG. 76), wicking elements, capillary tube or other devices on the cartridge 800 to allow body fluid to flow from the cartridge to the analyte detecting members 808 for analysis" ([0184]). "FIG. 74 shows a channel 826 that assists in drawing body fluid towards the analyte detecting members 808. ... Body fluid entering cavity 806, while

filling part of the cavity, will also be drawn by capillary action through the groove 826 towards the analyte detecting members 808" ([0187]). "With the analyte detecting members 808 located on the underside of the cartridge 800 as seen in the embodiment of FIG. 76, the cartridge 800 may include at least one through hole 834 to provide a passage for body fluid to pass from the cavity 806 to the analyte detecting member 808. The size, location, shape, and other features of the through hole 834 may be varied based on the cavity 806 and number of analyte detecting members 808 to be provided. In other embodiments, wicking elements or the like may be used to draw body fluid from the groove 826 to down to the analyte detecting member 808 via the through hole or holes 834" ([0189]).

As the Examiner pointed out, Boecker '995 further discloses "a spreading element 1190 which, along with at least one analyte detecting member underneath the element 1190, forms the bottom wall of the chamber 1150. As a non-limiting example, the element 1190 may have a mesh, a weaver, or "chainmail" type configuration. ... They may be configured morphologically in such a way as to wick blood exuding from the lancing site and direct the flow of the whole blood or the plasma content on to a sensor. ... The element 1190 may occupy the entire area over the analyte sensor, a portion, some geometric shape (round, rectangular, square, shapes with openings, figure eights, crisscrossed, gridded, etc.), or any combination of one or more of these configurations" ([0230], FIG. 120).

Thus, Boecker '009 and Boecker '995 teach using wicking elements such as channels and mesh carved on the bottom of the surface of the chamber to direct fluid to the through hole. However, there is no teaching in Boecker '009 and Boecker '995 of surface textures designed to account for surface tension (or contact angle), bulk properties (density, etc.) and surface flow of the cartridge. Since body fluid may spread all over the cartridge, such specifically designed surface texture is especially important for low volume sample collection where body fluid cannot be wasted on errant flows. In addition, Boecker '009 and Boecker '995 do not teach textures that are raised instead carved on the cartridge, which improves user feedback and sensation of contact.

Although Boecker '995 discloses a spreading element 190, it is formed/carved on the bottom wall of the chamber 1150 and is not an independent structure by itself that can be pushed and pierced by the penetrating member against the tissue in order

to draw fluid towards an analyte detecting member. Such separate and flexible mesh structure enables efficient fluid collection on the spot of the tissue/wound without waste and transportation of the fluid to the analyte detector over a distance especially when the wound being pierced cannot be placed in close proximity to the sample chamber. In addition, there is no teaching in Boecker '995 of various features of an independent mesh structure such as its ability to allow relaxation of the tissue, to increase cutting efficiency of the penetrating member, to reduce the amount of micropositioning used to assure that the droplet of the fluid gets to the analyte detecting member, to allow the fluid built up on tissue to be absorbed, to be made of capillary fibers, and to gradient type designed and patterned to create a desired movement of fluid in contact with the mesh.

Finally, neither Boecker '009 nor Boecker '995 discloses a commutator positioned to engage conductor material coupled to the sensory material to obtain analyte measurements.

The prior art distinguished

Independent claim 2 has been amended to include the language of:

wherein the texturing is designed to account for surface tension, bulk properties and surface flow of the cartridge.

Independent claim 5 has been amended to include the language of:

wherein the texture structure is designed to account for surface tension, bulk properties and surface flow of the cartridge.

Independent claim 6 has been amended to include the language of:

a plurality of mesh structures positioned pushed and pierced by the penetrating member against the tissue in order to draw fluid generated by said tissue towards one of the analyte detecting members.

Independent claim 11 includes the language of:

a conductor material coupled to the sensory material; and a commutator positioned to engage said conductor material to obtain analyte measurements measurements.

As discussed above, neither Boecker '009 nor Boecker '995 discloses 1) surface textures designed to account for surface tension, bulk properties, and surface flow of the cartridge; 2) a mesh structure pushed and pierced by the penetrating member against the tissue in order to draw fluid generated by said tissue towards one

of the analyte detecting members; 3) a commutator positioned to engage said conductor material to obtain analyte measurements. Thus, Boecker '009 or Boecker '995 cannot anticipate claims 2, 5, 6, and 11 or render them obvious. Since the rest of the claims rejected depend on claims 2, 5, 6, and 11, they are also allowable at least for depending from an allowable base claim. The Applicant respectfully requests all rejections with respect to these claims be withdrawn.

CONCLUSION

Applicant believes that the application is now in condition for allowance and respectfully requests the same.

The examiner is authorized to charge any fees due in connection with this paper to Deposit Account 50-4634 (PEL 2836).

Date: 4/16/10

135 Commonwealth Drive
Menlo Park, CA 94025
Tel: 650 752-3106
Customer No. 77845

Respectfully submitted,

GOODWIN PROCTER LLP

By: 

Paul Davis, Reg. No. 29,294